

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
93-R-0067

CUSTOMER NO.  
1168

FORM APPROVED  
OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

ALLERGAN  
P.O. BOX 19534  
IRVINE, CA 92713  
(714) 246-4484

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

## FACILITY LOCATIONS/sites

See Attached Listing

## REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO OF ANIMALS  (Cols. C + D + E)
4. Dogs	2	41	20	0	61
5. Cats	10	34	0	0	34
6. Guinea Pigs	5	0	55	0	55
7. Hamsters	0	0	0	0	0
8. Rabbits	0	797	2123	3	2923
9. Non-Human Primates	47	15	134	0	149
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					n/a

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

## CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

(B)(6) (B)(7)(c)

DATE SIGNED

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 93 - R - 0067
2. Number 3 of animals used in this study.
3. Species (common name) Rabbit of animals used in the study.
4. Explain the procedure producing pain and/or distress.

The procedure for this study involves the administration of a (b)(4) into the vitreous of the eye unilaterally in an animal (b)(4) in order to produce a model for (b)(4) in general the (b)(4) is mild to moderate and the animals appear to tolerate the condition quite well. They continue to eat and drink normally and display normal behavior. In the early stage of model development some of the early dose response testing resulting in (b)(4) and the animals appeared uncomfortable. Dose selection was adjusted to refine the model.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

This is a model to induce (b)(4) is commonly associated with pain and discomfort so by design the animal may be in some pain or discomfort. The purpose of the study is to evaluate new test compounds that will limit or alleviate the inflammation or discomfort so for most of the animals on study the discomfort is minimal. The control animals however by necessity of the scientific study cannot receive any (b)(4) treatment. Animals that were noted to have severe uveitis were treated with buprenorphine daily and supplemented with vegetables for a few days while (b)(4) and clinical signs associated with pain subsided, or euthanized if the problem did not subside. Buprenorphine has been demonstrated to have some (b)(4) activities (Volker, D., Bate, M., Gentle, R., and Garg, M., Oral buprenorphine is (b)(4) and modulates the pathogenesis of (b)(4) in the Lew/SSN rat, Lab Anim, 34 (2000) 423-429) so the chronic use of this drug for pain or discomfort would be incompatible with the scientific mission of this study. Chronic use of opioids for pain management is also thought to have effects upon appetite and body weight maintenance. For the animals with mild to moderate (b)(4) with no apparent clinical signs it was decided that it would not be prudent or scientifically sound to treat these animals using opioids.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency \_\_\_\_\_ CFR \_\_\_\_\_

NOV 20 2006